

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings in the Appendix following page 19 of this paper include an annotated sheet showing changes to Fig. 3 and formal drawings.

In Figure 3, previously omitted reference numerals 18 and 19 have been added.

Additionally, replacement sheets of drawings to replace all the informal drawings are in the Appendix.

No new matter has been added.

Attachments: Replacement Sheets for all the drawings

Annotated Sheet of FIG. 3 showing changes

REMARKS

The present communication responds to the non-final Office action of September 4, 2008 in which the Examiner rejected claims 1-38. Claims 1-21 and 24-38 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent 5,226,895 ("Harris") in view of U.S. Patent 6,582,408 ("Buch-Rasmussen et al."). Claims 22 and 23 were rejected under 35 U.S.C. § 103(a) as unpatentable over Harris in view of Buch-Rasmussen et al. and further in view of U.S. Patent 6,200,296 ("Dibiasi et al."). The Examiner also objected to the drawings and claim 10.

In response, claims 1, 5, 7, 9-11, 12, 16, 24, 29, 30, 33 and 35-38 have been amended, claims 22, 23 and 25 have been cancelled, without prejudice. New claims 39 and 40 have been added. No new subject matter has been added. Support for the claim amendments and new claims can be found in general throughout the specification and in particular, for example, at page 10 lines 3-14, page 13 line 22 to page 14 line 2, and page 24, line 17 to page 25, line 14.

The claim rejections are traversed in view of the amendments and for at least the reasons articulated below.

Reconsideration is requested.

Specification

Paragraphs 54-56, 63, 64 and 86 of Applicant's published patent application US 2004/0186441 A1 are amended to add the reference numeral 18 to the needle and reference numeral 19 to the piston.

Drawings

FIG. 3 has been amended to include a reference to needle 18 and piston 19. This change is supported by the specification at page 9, in the third full paragraph. The amendment to FIG. 3, as reflected in the attached annotated sheet and replacement sheet, address the Examiner's drawing objection.

Additionally, the drawings have been amended to replace the informal drawings with formal drawings.

Claim Objection

Claim 10 was objected to because it referred to itself. Claim 10 has been amended to depend from claim 9. Withdrawal of the objection is requested.

Obviousness-Type Double Patenting Rejections

Claims 1-38 were provisionally rejected on the ground of obviousness-type nonstatutory double patenting over claims 6-8, 16, 24, 26 and 27 copending U.S. Application 10/767,976.

A terminal disclaimer and the appropriate fee to overcome the obviousness-type nonstatutory double patenting rejection is submitted herewith.

Reconsideration and withdrawal of the non-obviousness type double patenting rejection are requested.

Claim Rejections under 35 U.S.C. § 103(a)

Harris in view of Buch-Rasmussen et al.

Claims 1-21 and 24-38 were rejected under 35 U.S.C. § 103(a) as unpatentable over Harris in view of Buch-Rasmussen et al.

Independent claims 1, 24, 37 and 38 have been amended to recite *inter alia* a disposable reservoir module or a reusable dosing and activating module, or both, claim 36 has been rewritten in independent form and recites *inter alia* a disposable reservoir module, and claim 25 has been cancelled.

Harris discloses a syringe including a housing for holding a container of liquid and a collar “received within the housing adjacent to the container second end for *permanently* retaining the container of liquid within the housing.” (*Harris, col. 2, lines 18-20, emphasis added*). Harris states that, “substitution of containers within the syringe [which] can contribute to the unethical use of the syringe in connection with non-prescribed substances.” (*Harris, col. 2, lines 3-6*). The injection device of Harris is not modular as recited in the independent claims.

The Examiner likens the two cap portions 86 and 100 of Harris to Applicant’s rear casing section, and also likens the cap 72 of Harris to Applicant’s dosing and drive device. Applicant’s rear casing section and dosing and drive device are separate elements, but Harris has one cap, with two portions of the same cap.

The cap of Harris 72 is a hollow two-piece cap, which has a proximal portion of the cap 86 and a distal portion of the cap 78 (*Harris, col. 4, lines 10-13 and FIG. 1*). Cap portion 100 is a modified distal portion of cap 72. (*Harris, col. 5, lines 13-16 and FIG. 3*). Therefore, the cap of Harris has a proximal portion 86 and a distal portion either 78 or 100.

Amended claim 1 recites, “a dosing and drive device movable rotationally about a rotational axis and translationally, relative to the front casing section, and when establishing a connection between the casing sections, is coupled to the driven member and said dosage setting member, such that a rotational movement of said dosing and drive device causes the dosing movement of the dosage setting member and a translation movement of the dosing and drive device causes the delivery movement of the driven member”

Amended claim 38 recites “a dosing and drive device moveable rotationally about a rotational axis and translationally relative to the front casing section, wherein, when connecting the casing sections, the dosing and drive device is coupled to the driven member and the dose setting member such that a rotational movement of the dosing and drive device causes the dosing movement of the dose setting member and a translation movement of the dosing and drive device causes the delivery movement of the driven member”

In the claims, the front and rear casing sections are separate elements from the Applicant’s dosing and drive device. Furthermore, the two cap portions 86 and 100 of Harris, which the Examiner likens to Applicant’s rear casing, “can be bonded by a conventional means such as ultrasonic welding or solvents or the like.” (*Harris, col. 5, lines 31-33*). Even if each cap portion is viewed as a separate element, they are bonded together, so movement of one cannot occur relative to the other.

Additionally, the Examiner likens Harris’ follower 104 to Applicant’s dosage setting member. However, instead of a dosage setting member, the principle function of follower 104 is to set a maximum allowable dose. (*Harris, col. 6, lines 19-20*). Furthermore, there are structural differences between the follower 104 of Harris and the Applicant’s dosage setting member. Follower 104 is adjusted to any position along threads 106. (*Harris, col. 6, lines 18-19*). The threads 106 are the threaded outer surface of distal portion 100 of cap 72. (*Harris, col. 5, lines 15-16*). Cap 72 includes two cap portions 86 and 100, which were likened to Applicant’s

rear casing section. The plunger rod 56 is inserted within the distal portion 100. (*Harris, col. 5, lines 25-26*). Instead of being connected to a piston rod, the follower 104 of Harris is engaged with the surface of the cap and the plunger rod is inserted into the cap.

Clearly, there are structural differences between the injection device of Harris and Applicant's administering apparatus as recited in the independent claims.

Furthermore, as accurately stated in the Office Action, Harris does not disclose an axial guide on a casing of the apparatus, nor does Harris disclose an axial guide that aligns the two casing sections.

Buch-Rasmussen et al. fails to remedy the disclosure deficiencies of Harris.

Buch-Rasmussen et al. is directed to a medication delivery device including a cartridge assembly and a dosing assembly. However, Buch-Rasmussen et al. discloses that the rod assembly 7 is part of the dosing assembly, not part of the cartridge assembly. (*Buch-Rasmussen et al., col. 4, lines 59-60*).

Accordingly, neither Harris nor Buch-Rasmussen et al. alone or in combination disclose or suggest the recitations of amended independent claims.

Reconsideration and withdrawal of the § 103 rejection of claims 1, 24, 36, 37 and 38 are requested.

Rejection of the Dependent Claims

Because claims 2-21 depend directly or indirectly from amended claim 1 and claims 26-35 depend directly or indirectly from amended claim 24 and incorporate all the limitations of the corresponding independent claims, they are allowable for the same reasons and, further, in view of their additional recitations.

Harris in view of Buch-Rasmussen et al. further in view of Dibiasi

Claims 22 and 23 were rejected under 35 U.S.C. § 103(a) as unpatentable over Harris in view of Buch-Rasmussen et al. and further in view of Dibiasi et al.

Claims 22 and 23 have been cancelled, thereby obviating the rejection thereof.

New Claims

New claims 39 and 40 have been added, without adding new matter. Support can be found in general throughout the specification and, in particular, for example, at page 24, line 17 to page 25, line 14.

Since new claims 39 and 40 depend directly from amended claim 1 and incorporate all the limitations of amended claim 1, they are allowable for the same reasons and, further, in view of their additional recitations.

Claim 39 is directed to the administering apparatus of claim 1, wherein the piston rod is held by a mechanism holder, secured against rotating.

Claim 40 is directed to the administering apparatus of claim 1, wherein the dosage setting member completes a rotational dosing movement and a translational dosing movement relative to the front casing section during dosing while the piston rod remains stationary.

Conclusion

This paper is being submitted on or before March 4, 2009, and an extension of time until that date is requested. This paper also generates new claims fees. The fees for the extension of time and the new claims should be charged to Deposit Account No. 04-1420. The Commissioner is also authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application is now in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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